REMARKS

The requested deletion of the hyperlink reference has been made. It is noted that the restriction requirement has been made final and that the only claims under consideration are claims 23 –27.

Claim Rejections- 35 USC sec. 112

The rejection suggests that the term "specifically" as applied to an antibody is not clear as to the proper boundary. In the subsequent paragraphs of the Office Action the rejection recognizes that the preparation of antibodies is a well-ploughed field. The meaning of "specifically" is amply exemplified in the specification. The Examiner's attention is directed to pages 16-19, where the method of preparation of the antibodies is described and their use in immunoassays. By specifically is intended that the antibodies would find use in immuoassays. For example, on page 18, lines 23-27, wash steps are described where "non-specifically bound proteins" are washed away. This an ample demonstration of what is intended by the term "specifically." Particularly, when one considers the context is the use of antibodies, where those of skill in the art are well aware of the requirements of an acceptable binding affinity, the language is considered to be definite and provides a clear statement as to the scope. The Examiner is respectfully requested to withdraw this rejection.

The Examiner inquires whether an antibody made to the sequence described in Maucuer is within the scope of the claim. In order to answer this question the entire claim must be considered. The claims require that the antibody be to the wild-type TSG 101. Since the polypeptide sequence in the reference is deduced from the nucleic acid sequence, the polypeptide was never made by Macuer. Therefore, Macuer could not make an antibody from a deduced sequence. Without having made the deduced polypeptide, prepared antibodies with the deduced polypeptide and tested such antibody composition(s) against wild-type TSG 101, it is speculative to suggest whether an antibody actually prepared from the deduced polypeptide would come within the claim.

The rejection states that "wild-type" and "mammalian" are genus categories that contain a large number of unpredictable species. It can be stated without citation that the claims are subject to a reasonableness standard. Claims cannot be more definite than the particular technology will allow. It is well recognized that "wild-type" refers to a natural source. To the extent that alleles are present in a substantial proportion of the population, as distinguished from a mutation that may be present in an individual or small group, then such proteins are wild-type and would come within the scope of the subject claims. The Examiner is respectfully requested to withdraw this rejection.

So far as the term "mammalian," the genus is well accepted. The rejection makes the bald statement that two species is not enough to support the genus. As is evidenced by the two sequences, they are very similar. Mice and humans are sufficiently distant in the evolutionary sequence to suggest that other mammalian species would have similar

sequences. Therefore, antibodies prepared to the described sequences would be paradigmatic for the other mammalian species. As has been recently established, genes are highly conserved among species and the number of genes in the genotype do not differ that greatly between the slug and man. As such, having provided two disparate species, applicants should be permitted to claim the genus. There is a large number of patents where the same exemplification has permitted claiming the same genus, particularly where applicants are the first to identify the protein and the claims are directed to antibodies for the protein, regardless of the mammalian species. The Examiner is respectfully requested to withdraw the rejection.

Claim Rejections – 35 USC sec. 103

Claims 23 – 26 are rejected based on Macuer in view of Campbell and Levinson. Since the latter two references are cited to show the fact that preparation of antibodies is now routine once the protein is available, only Macuer will be discussed. As the Examiner may have anticipated from the above discussion, Macuer never had the polypeptide and therefore could not have made antibody to his deduced peptide sequence. Furthermore, having only a fragment of the sequence for the protein, there is no way to establish whether expression of the fragment in any chosen host would have provided a peptide that could have been used to prepare antibodies that would be cross-reactive with the wild-type protein.

Levinson is cited as saying that one can make an antibody to a pentapeptide. However, the antibody would bind to the pentapeptide. Levinson cannot be cited for the proposition that the antibody would bind to the intact protein from which the pentapeptide was derived. As such, Macuer cannot be found to suggest the subject antibodies. The Examiner must speculate as to whether Macuer would have actually prepared the peptide encoded by his nucleic acid sequence and then have found some reason to prepare antibodies to the sequence or fragment thereof.

In order for a reference to suggest a subject invention, there must be some incentive to use the disclosure in the manner taught by the claimed invention. The incentive is solely provided by the subject disclosure and not by anything in Macuer. Macuer is interested in peptides that bind to stathmin. Macuer does not suggest that the disclosed deduced peptide would or should be used to prepare antibodies. Macuer indicates that the proteins found to interact with stathmin should be further characterized to determine how they interact with stathmin and their physiological role.

A reference should not be a basis for speculation based on the teaching of the application. The fact that the capability exists for making antibodies, does not make antibodies for a protein obvious for every "est." This would deprive any future discoverer of the protein of the fruits of his/her invention. Discovering and identifying a new protein is a major effort, involving isolation, purification and identification. Only after these stages have been achieved is it possible to prepare antibodies known to bind to the particular protein. In the case of Macuer, none of these steps are performed. In the absence of any peptide having been prepared, any antibody having been prepared, and/or

any suggestion that antibodies should be prepared, the Examiner is respectfully requested to withdraw the rejection.

The remaining rejection of claims 26 and 27 cites the same references as above and adds Harlow as teaching the additional limitations of these claims. For the reasons given above, these claims are patentable. In addition, in the absence of having the protein and understanding its importance, there would have been no incentive to modify the antibodies in the manner claimed.

In view of the above amendment and remarks, the claims under consideration are deemed to be allowable and the Examiner is respectfully requested to allow these claims. In the event that these claims are allowed, the Examiner is authorized to cancel the remaining claims and pass this application to issue.

Respectfully yours,

Bertram I. Rowland
Reg. No. 20,015